IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION | ) | MDL NO. 1203 |
| THIS DOCUMENT RELATES TO: | ) | |
| SHEILA BROWN, et al. | ) | |
| v. | ) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION | ) | 2:16 MD 1203 |

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8510**

Bartle, C.J. July 29, 2010

Jean Davis ("Ms. Davis" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2001, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Michael N. Rubinstein, M.D., F.A.C.C. Dr. Rubinstein is no stranger to this litigation. According to the Trust, Dr. Rubinstein has signed at least 213 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated April 28, 1999, Dr. Rubinstein attested in Part II of claimant's Green Form that Ms. Davis suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 40% to 49%.[3] Based on

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Rubinstein also attested that Ms. Davis suffered from New
(continued...)

such findings, claimant would be entitled to Matrix B-1,[4] Level II benefits in the amount of $81,547.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, Raymon K. Nelson, M.D., stated that claimant had moderate mitral regurgitation. Dr. Nelson, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

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3. (...continued)
York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

4. Ms. Davis ingested Diet Drugs for less than 61 days. Thus, Ms. Davis concedes that, if eligible, her claim would be paid on Matrix B-1.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

Wyeth selected this claim for audit,[6] and the Trust forwarded the claim for review by Ernest C. Madu, M.D., F.A.C.C., F.E.S.C., one of its auditing cardiologists. In audit, Dr. Madu concluded that there was no reasonable medical basis for Dr. Rubinstein's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Madu determined that claimant's echocardiogram demonstrated "no more than physiologic mitral regurgitation."[7] Dr. Madu further observed in the Auditing Cardiologist Worksheet: "[v]ery poor quality study with most standard views absent" and "[v]ery high gain setting and poor doppler evaluation."

Based on the auditing cardiologist's finding that claimant had physiologic mitral regurgitation, the Trust issued a post-audit determination denying this claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show

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6. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. & VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, Wyeth identified for audit the level of claimant's mitral regurgitation. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

7. As noted in the Auditing Cardiologist Worksheet, physiologic mitral regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or $\leq$ 5% RJA/LAA."

cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2457, Audit Policies and Procedures § IV.C.[8] The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5237 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 13, 2005. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, Gary J.

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8. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457. Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to this claim.

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Davis argues that there is a reasonable medical basis for Dr. Rubinstein's representation that claimant had moderate mitral regurgitation and that the auditing cardiologist, Dr. Madu, was "mistaken" in finding only physiologic mitral regurgitation. To that end, claimant submitted videotaped statements under oath of Dr. Rubinstein, Mark M. Applefeld, M.D., F.A.C.C., and Duncan Salmon, M.D. wherein each cardiologist explains how he concluded that claimant had moderate mitral regurgitation. Claimant also submitted curricula vitae for these physicians. In addition, claimant submitted Part II of Green Forms completed by Dr. Rubinstein, Dr.

Applefeld, and Dr. Salmon, which were based on claimant's April 28, 1999 echocardiogram. Each cardiologist concluded that claimant had moderate mitral regurgitation. Dr. Salmon specifically observed: "study difficult but in apical 2-chamber study [mitral regurgitation] is seen filling 20% of [left atrium]." Moreover, claimant submitted a number of still-frame images taken from her April 28, 1999 echocardiogram, which claimant argues show "systolic, apical mitral regurgitation of a moderate degree."

Claimant also argues that this court in PTO No. 2640 (Nov. 14, 2002) and Harvey Feigenbaum, M.D. in the fifth edition of Echocardiography explained that a cardiologist should use the "maximum or largest regurgitant jet ... when quantifying the degree of mitral regurgitation." Claimant further suggests that a cardiologist should include in his or her measurement "'the entire mitral regurgitant jet, including the surrounding, lower flow spray.'" In addition, claimant submits that the degree of regurgitation demonstrated by an echocardiogram performed on a Diet Drug Recipient may vary within the same study because of the typical patient size. Finally, claimant asserts that: (1) her echocardiogram should be viewed more favorably because it was conducted in the normal course of treatment rather than in anticipation of submitting a claim; (2) the proper technique for reviewing echocardiograms is to employ a stop action and slow motion method; (3) the limitations of echocardiography dictate that if moderate mitral regurgitation is present at any point in

the study, it is present throughout the study; (4) inter-reader variability may account for the difference of opinion among cardiologists; (5) the auditing cardiologist should not simply substitute his opinion for that of the attesting physician; and (6) three cardiologists reviewed her echocardiogram and found that she had moderate mitral regurgitation and, therefore, there is a reasonable medical basis for her claim.[10]

In response, the Trust argues that the opinions of Dr. Applefeld and Dr. Salmon do not establish a reasonable medical basis for Dr. Rubinstein's representation that claimant had moderate mitral regurgitation because they "merely repeat" his finding. In addition, the Trust asserts that claimant "selectively quotes Feigenbaum" in support of her assertion that low velocity flow is appropriately included in the measurement of the regurgitant jet. The Trust submits that Feigenbaum instructs that only high velocity flow should be included in the mitral regurgitant jet, and low velocity flow should be excluded. The Trust further contends that the auditing cardiologist thoroughly reviewed claimant's echocardiogram and determined that there was no reasonable medical basis for the attesting physician's finding

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10. Claimant also argues that, in reviewing her claim, the court should consider that certain claims have passed audit "mistakenly" and that certain auditors have been removed for undisclosed conflicts. We disagree. Claimant does not attempt to explain how these circumstances had any impact on Dr. Madu's review of her specific claim. As we consistently have stated, the relevant inquiry is whether a claimant has established a reasonable medical basis for his or her claim, an inquiry that is to be made on a claim-by-claim basis. See, e.g., PTO No. 6280 at 9 (May 19, 2006).

of moderate mitral regurgitation. Finally, the Trust argues that inter-reader variability does not account for the differences in the opinions of the cardiologists here.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Specifically, Dr. Vigilante stated that:

> Color flow doppler of the apical four chamber view demonstrated only trace mitral regurgitation. In the apical two chamber view, only mild mitral regurgitation was noted with a jet just slightly above the mitral closure line. The RJA/LAA was less than 10% in all cardiac cycles.
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> The RJA/LAA did not come close to 20%. Even taking into account the issue of inter-reader variability, it would be impossible for a reasonable echocardiographer to conclude that moderate mitral regurgitation was present on the echocardiogram study of April 28, 1999.

In response to the Technical Advisor Report, claimant argues that this court should not accept Dr. Vigilante's determination because he "fail[ed] to measure the regurgitant jet on multiple occasions." In addition, Ms. Davis suggests that Dr. Vigilante "apparently ignored" the still-frame images she submitted, and that a Technical Advisor should be required to make measurements when still-frame images are submitted by a

claimant.[11] Finally, claimant asserts that Dr. Vigilante reviewed claimant's echocardiogram at normal speed without employing the "slow motion review."[12]

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we reject claimant's argument that the still-frame images claimant submitted demonstrate a reasonable medical basis for the attesting physician's finding that Ms. Davis had moderate mitral regurgitation. Dr. Madu reviewed claimant's echocardiogram and concluded that it demonstrated "no more than physiologic mitral regurgitation."[13] Dr. Vigilante also reviewed claimant's echocardiogram and concluded that it did not demonstrate moderate mitral regurgitation. Specifically, Dr. Vigilante observed that "[c]olor flow doppler of the apical four chamber view demonstrated only trace mitral regurgitation. In the apical two chamber view, only mild mitral regurgitation was noted with a jet just slightly above the mitral closure line." Moreover,

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11. Claimant also asserts, without any support, that Dr. Vigilante should recuse himself from any proceeding in which Dr. Applefeld serves as the attesting physician. As Dr. Applefeld was not the attesting physician in this claim, we need not address this issue.

12. There is nothing in the record indicating or suggesting that Dr. Vigilante did not appropriately assess claimant's level of regurgitation. Thus, we will not consider her contention in this regard.

13. Given Dr. Madu's specific finding, we disagree with claimant that the auditing cardiologist simply substituted his opinion for that of the attesting physician.

Dr. Vigilante determined that "[t]he RJA/LAA was less than 10% in all cardiac cycles."

Although still frames are necessary to determine a claimant's level of mitral regurgitation, they alone are not sufficient. See PTO No. 6897 at 7 (Jan. 26, 2007). Indeed, we have determined that "'[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved.'" Id. (quoting PTO No. 2640 at 9). As stated previously, moderate mitral regurgitation is present where the RJA/LAA in any apical view is equal to or greater than 20%. See Settlement Agreement § I.22. Based on Dr. Vigilante's specific determination that claimant's "RJA/LAA did not come close to 20%," these still-frame images alone do not provide a reasonable medical basis for Dr. Rubinstein's representation that claimant suffered from moderate mitral regurgitation.[14]

In addition, claimant's argument that the presence of moderate mitral regurgitation at any point in the study dictates

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14. Similarly, we disagree with claimant that the Technical Advisor "ignored" the still-frame images she submitted. Notably, Dr. Vigilante stated in the Technical Advisor Report that "[t]en colored still frames were also reviewed." In addition, the Technical Advisor is not required to make specific measurements when still-frame images are submitted by a claimant. We also decline to disregard the Technical Advisor Report because, according to claimant, Dr. Vigilante did not "measure the regurgitant jet on multiple occasions." This assertion is inconsistent with Dr. Vigilante's specific finding that claimant's mitral regurgitation was less than 10% in all cardiac cycles.

that it is present throughout the study is misplaced.[15] We previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram." PTO No. 6997 at 11 (Feb. 26, 2007). "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." Id.

We also disagree with claimant that "lower flow spray" is considered mitral regurgitation. We have consistently held that conduct "beyond the bounds of medical reason" can include over-manipulating echocardiogram settings and characterizing low velocity flow as mitral regurgitation. PTO No. 2640 at 11-13, 15, 22, 26. We have further found that "[o]n a color flow Doppler echocardiogram, mitral regurgitation will thus display as a high velocity, mosaic blue/green teardrop shaped jet that borders the mitral valve leaflets and expands into the left atrium throughout at least a portion of systole." Id. at 10-11 (footnote omitted). There is nothing to indicate that including low velocity flow as mitral regurgitation is permissible under the Settlement Agreement. Significantly, claimant does not contest that her physicians included low velocity flow as mitral

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15. In any event, as Dr. Vigilante determined that "[t]he RJA/LAA was less than 10% in all cardiac cycles," the still-frame images submitted by Ms. Davis cannot establish a reasonable medical basis for her claim.

regurgitation in determining that she had moderate mitral regurgitation. Moreover, Dr. Madu determined that the claimant's echocardiogram had a "[v]ery high gain setting." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.[16]

Finally, to the extent claimant argues that inter-reader variability accounts for the difference in the opinions of the attesting physician and the auditing cardiologist, such argument is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the opinions of claimant's cardiologists cannot be medically reasonable where the auditing cardiologist and Technical Advisor concluded that claimant's mitral regurgitation was physiologic and less than 10%, respectively. To conclude otherwise would allow a claimant with less than moderate mitral regurgitation to receive Matrix Benefits at Level II. This result would render meaningless the standards established in the Settlement Agreement.

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16. For this reason as well, we reject claimant's arguments that there is a reasonable medical basis for her claim because the echocardiogram on which the Green Form representations were based was performed during the course of regular treatment.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of the claim of Ms. Davis for Matrix Benefits.